

## **REMARKS**

Claim 1 has been amended, new claims 25-27 have been added, and claims 7, 23, and 24 have been cancelled without prejudice or disclaimer. Claims 1, 17, and 25-27 are pending in the instant application. No new matter has been added as a result of the above-described amendments. Applicants note that new claims 25-27 correspond to recently allowed claims 23-25 of U.S. Application No. 10/646,633. Support for these claims can be found in the specification at, for example, page 5, lines 23-26 and page 8, lines 31-33. The objections and rejections set forth in the Office Action have been overcome by amendment.

### **1. Rejection of claim 24 under 35 U.S.C. § 112, second paragraph**

The Office Action asserts a rejection of claim 24 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. In particular, the Action states that claim 24 recites a reagent in which nucleic acid fragments "are removed by washing" at particular conditions, but that it is not clear how this method limitation relates to the claimed reagent.

Applicants have cancelled claim 24, rendering this ground of rejection moot. Applicants, therefore, respectfully request that this ground of rejection be withdrawn.

### **2. Rejections of claims 1, 7, 17, 23, and 24 under 35 U.S.C. § 112, first paragraph**

#### **a. Rejection of claims 7 and 23 as containing new matter**

The Office Action asserts rejections of claims 7 and 23 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention.

#### **i. Claim 23**

The Action asserts that the limitation that "the proportion of total HPV DNA in the reagent that comprises labeled nucleic acid fragments of the first genomic HPV DNA probe set and the proportion of total HPV DNA in the reagent that comprises labeled nucleic acid fragments of the third genomic HPV DNA probe set are decreased relative to the proportions of the total HPV DNA

in the reagent that comprise labeled nucleic acid fragments of the other HPV DNA probe sets" in claim 23 constitutes new matter. The Action states that the specification provides a single example encompassed by claim 23, but does not discuss or contemplate the broad genus of reagents recited in the claim. The Action also states that no specific basis for the limitation could be found in the specification, and concludes that claim 23 incorporates new matter.

Applicants have cancelled claim 23, rendering this ground of rejection moot. Applicants, therefore, respectfully request that this ground of rejection be withdrawn.

ii. Claim 7

The Action asserts that the recitation of the term "about" prior to the statement of the percentages of total HPV DNA in the reagent for each of the plurality of nucleic acid fragments in claim 7 constitutes new matter. The Action states that the specification does not provide any basis for modifications that are "about" each of the recited percentages. The Action also states that the recitation of, for example, "about 8.3%" encompasses percentages that are above and below the recited numbers, but that the specification only contemplates "8.3%" and not "about 8.3%."

Applicants have cancelled claim 7, rendering this ground of rejection moot. Applicants, therefore, respectfully request that this ground of rejection be withdrawn.

Applicants contend that the new matter rejections have been overcome by amendment, and therefore, respectfully request that these rejections be withdrawn.

b. Rejection of claims 1, 17, 23, and 24 under the written description requirement of 35 U.S.C. § 112, first paragraph

The Office Action contains a rejection of claims 1, 17, 23, and 24 under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. The Action states that while the specification describes a single reagent that meets the functional limitations of claim 1 (*i.e.*, the reagent described in Example 1 having the percentages listed in Table 2), the claims are much broader than what is described in the specification with regard to what nucleic acid is required to be

in the probe and how much of that nucleic acid must be in the probe. The Action also states that the claims are inclusive of genomic HPV DNA probe sets at any concentration relative to one another, and further, are inclusive of additional probe sets within the reagent since claim 1 recites "[a] reagent . . . comprising a plurality of genomic HPV DNA probe sets." The Action further states that while claim 23 requires that the genomic HPV DNA probe sets for HPV types 16 and 31 have lower representation in the reagent than the other recited probe sets, this claim allows for any possible proportions within this generic requirement. The Action further states that while Applicants are clearly in possession of a reagent comprising probe sets produced by nick-translation of the full-length genome of six separate plasmids, each plasmid containing the whole genome of HPV types 16, 18, 31, 33, 35, or 51, wherein the probe sets derived from HPV types 18, 33, 35, and 51 are present at 0.5 ng/mL and the probe sets derived from HPV types 16 and 31 are present at 0.2 ng/mL, the claims encompass hundreds of thousands of possible reagents.

Applicants have cancelled claims 23 and 24, and have amended claim 1 to recite that the individual genomic HPV DNA probe sets comprise a plurality of labeled nucleic acid fragments constituting approximately 8.3% or 20.8% (depending on the HPV type from which the probe set is derived) of the total HPV DNA in the reagent. Applicants note that a reagent containing 8.3% of HPV types 16 and 31 and 20.8% of HPV types 18, 33, 35, and 51 contains 99.8% HPV DNA. Thus, Applicants have amended claim 1 to recite that the reagent contain "approximately 8.3%" and "approximately 20.8%." Applicants contend that the recitation of the term "approximately" does not introduce new matter or render claim 1 indefinite since one of ordinary skill in the art would recognize that the percentages recited in Table 2 must be approximate values since the total amount of HPV DNA in the reagent described in Example 1 must be 100% (this must be true regardless of the amount of each genomic HPV DNA probe set added to the reagent). In view of the cancellation of claims 23 and 24, and the amendment of claim 1 (rejected claim 17 depends from claim 1), Applicants respectfully request that this ground of rejection be withdrawn.

Applicants contend that the rejection based on the written description requirement of 35 U.S.C. § 112, first paragraph, has been overcome by amendment, and therefore, respectfully request that this rejection be withdrawn.

c. Rejection of claims 1, 17, 23, and 24 under the enablement requirement of 35 U.S.C. § 112, first paragraph

The Office Action asserts a rejection of claims 1, 17, 23, and 24 under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention. The Action states that while the specification is enabling for the reagent of claim 7, it does not provide enablement for reagents having different proportions of HPV probe sets and which retain the functional properties recited in the claims. The Action also states that it would require undue experimentation to make and use the claimed invention commensurate in scope with claims.

As described above in section 2(b), Applicants have cancelled claims 23 and 24, and have amended claim 1. In view of cancellation of claims 23 and 24, and the amendment of claim 1 (rejected claim 17 depends from claim 1), Applicants respectfully request that this ground of rejection be withdrawn.

Applicants contend that the rejection based on the enablement requirement of 35 U.S.C. § 112, first paragraph, has been overcome by amendment, and therefore, respectfully request that this rejection be withdrawn.

**CONCLUSIONS**

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

If Examiner Switzer believes it to be helpful, she is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,  
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